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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,982	RUGGERO ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-19,25-27,30,34-40,43,46-48 and 51-56* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 8-10, 13-19, and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are) 3-6, 11, 12, 25, 26, 30, 34-40, 43, 46-48, and 5-56.

DETAILED ACTION

Status of the Claims

This Office Action is in response to Applicant's Restriction Requirement remarks filed on November 11, 2008. Claim(s) 1-6, 8-19, 25-27, 30, 34-40, 43, 46-48, and 51-56 are pending. Claim(s) 3-6, 11, 12, 25, 26, 30, 34-40, 43, 46-48, and 5-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election of Group I drawn to a method of treating Parkinson's disease and election of species of safinamide (first composition) and levodopa (second composition) without traverse of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 1, 2, 8-10, 13-19, and 27 are examined herein insofar as they read on the elected invention and species.

Objections

Claim 17, the drug "amantadine" is misspelled "amantidine". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 8-10, 13-19, and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for safinamide as the MAO-B inhibitor, does not reasonably provide enablement for the treatment of Parkinson's disease with any MAO-B inhibitor as set forth in the instant claims. The specification does not provide sufficient information that all MAO-B inhibitors are capable of treating Parkinson's disease. Thus, the term "MAO-B inhibitor" is very broad as cited in claims 1, 2, 8-10, 13-19, and 27.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide sufficient information that all MAO-B inhibitors are capable of treating Parkinson's disease.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence

or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treating Parkinson's disease with the administration of any MAO-B inhibitor as described in claims 1, 2, 8-10, 13-19, and 27.

The nature of the invention is complex in that it encompasses the treatment said ailments using a wide array of compounds encompassed by the term "MAO-B inhibitor".

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass methods of treating Parkinson's disease by administering by a wide array of compounds encompassed the term "MAO-B inhibitor". There are countless possible compounds encompassed by "MAO-B inhibitor" for the treatment claimed. The claims are therefore much broader than the enabling disclosure.

(3). Guidance of the Specification:

There no guidance given on any MAO-B inhibitor other than safinamide.

(4). Working Examples:

Applicant provides clinical studies with only safinamide and some efficacy studies with patients pretreated with a "dopamine agonist", however it is not clear exactly which one it is.

(5). State of the Art:

The state of the art with regard to MAO-B inhibitors is high. The state of the art with regard to any and al MAO-B inhibitors treating Parkinson's disease is low.

(6). Nature and predictability of the invention

The nature of the invention is directed towards medicine and is therefore physiological in nature. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a combination of an appropriate pharmaceutical carrier, a dosage for each compound as encompassed by "MAO-B inhibitor", the duration of treatment, route of treatment, etc. and, in the case of human treatment, an appropriate animal model system for one of the claimed compounds. One would

then need to test the combination in the model system to determine whether or not the combination is effective for treating Parkinson's disease. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art Parkinson's treatment with any MAO-B inhibitor, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to treating Parkinson's disease by administration of any MAO-B inhibitor as set forth in the claims.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, methods of treating Parkinson's disease by administering any MAO-B inhibitor of the claims are not considered to be enabled by the instant specification.

Claims 1, 2, 8-10, 13-19, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. It is not clear from the specification what the Parkinson's disease agent is that the Applicant used in the clinical studies. Furthermore, Applicant has not provided any guidance that a few combinations much less that all combinations of safinamide or derivatives thereof with any Parkinson's disease agent are effective at treating Parkinson's disease. Based on the specification, it is not clear that Applicant had possession of the instant invention at the time the application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 are rejected under 3 5 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 14 recite "levodopa/PDI". There is nowhere in the application that provides the definition of the expanded notation of "PDI".

Claim 14 contains the trademark/trade names SINEMET®, SINEMET-CR®, MADOPAR®, and MADOPAR-HB®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or

product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe levodopa plus carbidopa, levodopa plus controlled release carbidopa, levodopa plus benserazide, and levodopa plus controlled release benserazide, respectively, and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 18, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Fredriksson et al. (*Journal of Neural Transmission*, 1999).

Fredriksson teaches that the administration of safinamide (aka FCE 26743) and levodopa reduces the parkinsonian symptoms in mice with MPTP-induced parkinsonism (abstract; page 892, see "experimental design and procedure", specifically "FCE 26743+L-Dopa experiment"; page 894, see "results", specifically "effect of FCE 26743", see "discussion; page 906, 1st full paragraph), meeting the limitations of claims 1, 2, 18, and 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 9, 10, 13, 14, and17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fredriksson et al. (*Journal of Neural Transmission*, 1999) as applied to claims 1, 2, 18, 19 above in view of Edgren (US Patent No. 6,217,905 B1).

Fredriksson is discussed above.

Fredriksson does not teach the administration of more than one Parkinson's disease agents.

Edgren teaches the administration of at least one drug over a prolonged period of time in the treatment of Parkinson's disease (column 2, lines 9-11).

Edgen teaches a number of well known agents that are useful for treating Parkinson's disease, namely bromocriptine; bromocriptine and its therapeutically acceptable salts; bromocriptine mesylate; ergot derivatives including lisuride, pergolide, and mesulergine; levodopa; carbidopa; levodopa/carbidopa; amantadine; eldepryl (also known as selegilene); trihexyphenidyl; benztropine; biperiden; ethopropazine; procyclidine; dopamine agonist, monamine oxidase inhibitors, anticholinergic including benztropine mesylate, trihexyphenidyl hydrochloride, procyclidine hydrochloride, biperiden hydrochloride, and ethopropazine hydrochloride; and the like (column 5, lines 5-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the combination of safinamide and levodopa for

the treatment of Parkinson's as taught by Fredriksson and also administered additional Parkinson's disease agents as taught by Edgen. It would be obvious to add additional agents that are known in the art to treat the same disease. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fredriksson et al. (*Journal of Neural Transmission*, 1999) as applied to claims 1, 2, 18, 19 above in view of Chenard (US Patent No. 6,258,827 B1).

Fredriksson is discussed above.

Fredriksson does not teach the composition further comprising a catechol-*O*-methyltransferase inhibitor, such as tolcapone or entacapone.

Chenard teaches that there are classes of compounds reported as being useful in the treatment of Parkinson's disease namely, among others, D1, D2 agonists, monoamine oxidase-B inhibitors, levodopa and COMT inhibitors (column 12, lines 31-45), wherein COMT inhibitors include tolcapone and entacapone (column 13, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the combination of safinamide and levodopa for

the treatment of Parkinson's as taught by Fredriksson and also administered additional Parkinson's disease agents such as tolcapone or entacapone as taught by Chenard. Because such agents are well known in the art to treat the same disease, it would have been obvious to one in the art to have combined them. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Claims 1, 2, 8-10, 13-19, and 27 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617